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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,471	07/27/2001	Leland F. Wilson	9050-0053	3484

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,471	WILSON ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,26-28,43 and 50* is/are pending in the application.

4a) Of the above claim(s) *13-15 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,16-18, 20-24, 26-28, 43, and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed April 21, 2004 have been entered. Claims 25, 29-42, 44-49, and 51-61 are cancelled. Claims 13-15 and 19 are withdrawn from consideration as they are drawn to non-elected specie.

The outstanding rejections under 35 USC 112, first paragraph are withdrawn in view of the amendments and remarks filed April 21, 2004.

The outstanding rejection under 35 USC 103 is withdrawn in view of the cancellation of claims 29-42. A new ground of rejection is set forth below.

Claims 1-12,16-18, 20-24, 26-28, 43, and 50 are examined on the merit herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12,16-18, 20-24, 26-28, 43, and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 31-37, 46, 49, and 54 of copending Application No. 09/919,472. '472

teaches a method of enhancing female sexual desire by administering an androgenic agent combining with a secondary agents such as the one herein claimed.

'472 does not expressly teach the regimen of how and when to administer the androgenic compounds and the secondary active to enhance female sexual desires.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed regimen of androgenic compounds and the secondary active to enhance female sexual desires.

One of ordinary skill in the art would have been motivated to employ the herein claimed regimen of androgenic compounds and the secondary active to enhance female sexual desires. The optimization of the result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12,16-18, 20-24, 26-28, 43, and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for serotonin antagonists disclosed in page 16, lines 3-8 of the instant specification, does not reasonably provide enablement for other serotonin antagonists. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define a suitable "serotonin antagonists" for use in the instant method. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. For example, it is not clear what the degree of serotonin antagonism that a compound possesses would be useful for the instant method. There is no structural or chemical/physical criteria disclosed. In the instant case, only a limited

number of "serotonin antagonists" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The physiological function and properties of serotonin antagonists are often different depending on the different subtypes of serotonin the agent interacts and thus, the use of any compounds that antagonizes at serotonin receptor for treating female sexual dysfunction is unpredictable. Such use would require each embodiment to be individually assessed for physiological activity. The instant claims are so broad that they read on all "serotonin antagonist(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-12,16-18, 20-24, 26-28, 43, and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for potassium channel openers disclosed in instant specification, page 16, lines 18-21, does not reasonably provide enablement for other suitable potassium channel openers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. IN the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set

forth the eight factors to consider when assessing if a disclosure would have required undue experimentation (See above for the eight factors).

Applicant fails to set forth the criteria that define a suitable "potassium channel openers" for use in the instant method. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. For example, it is not clear what the degree of affinity to potassium channel that a potassium channel openers would be useful for the instant method. There is no structural or chemical/physical criteria disclosed. In the instant case, only a limited number of "potassium channel openers" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The physiological function and properties of potassium channel and its different receptor subtype are not even fully understood and thus, the use of any compounds that is potassium channel opener for treating female sexual dysfunction is unpredictable. Such use would require each embodiment to be individually assessed for physiological activity. The instant claims are so broad that they read on all "potassium channel opener(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-12,16-18, 20-24, 26-28, 43, and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for potassium channel

openers disclosed in instant specification, page 16, lines 22-28, does not reasonably provide enablement for other suitable potassium channel openers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. IN the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation (See above for the eight factors).

Applicant fails to set forth the criteria that define a suitable "potassium channel blockers" for use in the instant method. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. For example, it is not clear what the degree of affinity to potassium channel that a potassium channel blockers would be useful for the instant method. There is no structural or chemical/physical criteria disclosed. In the instant case, only a limited number of "potassium channel blockers" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The physiological function and properties of potassium channel and its different receptor subtype are not even fully understood and thus, the use of any compounds that is potassium channel blocker for treating female sexual dysfunction is unpredictable. Such use would require each embodiment to be individually assessed for physiological activity. The instant claims

are so broad that they read on all "potassium channel blocker(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12,16-18, 20-24, 26-28, 43, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions "phenoxyphenylacetic acids and derivatives thereof" and tryptophan and derivatives thereof" [emphasis added] recited in claim 1 render the claim indefinite as to what compounds are encompassed thereby. The instant specification does not disclose what compounds as the derivatives of the agents. In pages 18 and 19 of the instant specification merely disclose the salt, ester, and amide of the herein claimed compounds. It is not clear to one of ordinary skill in the art what the metes and bounds of the claims would be.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12,16-18, 20-24, 26-28, 43, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (WO 99/66909) in view of Fuxe (US Patent 3,917,841), Adams is reference of record.

Adams teaches a method of treating female sexual dysfunction employing an androgenic agent such as dihydrotestosterone and its ester and apomorphine (See claims 1-3, 11-12). Adams also teaches that the androgenic agent may be administered orally (See page 21, line 13-25). Adams also teaches that

dihydrotestosterone may be administered prior to or concomitantly with apomorphine (See claims 16-17). Adam also teaches that 480μg/kg dose of one of the androgenic agent, testosterone, 36 hours prior to the administration of apomorphine are effective to alleviate sexual dysfunction or normalize sexual dysfunction in post-menopausal and pre-menopausal women (See page 32, line 10-23).

Adams does not expressly teach the androgenic agent is dihydrotestosterone propionate. Adams does not expressly teach the addition agent to be administered parenterally. Adams does not expressly teach the dosing regimen and dosage of the androgenic agent and the secondary active herein.

Fuxe teaches a method of enhancing female libido by employing dopaminergic blockers such as spiroperidol (See claims 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ dihydrotestosterone propionate with a second active agent such as spiroperidol, in the dosage range and regimen herein, in the method of treating female sexual dysfunction.

One of ordinary skill in the art would have been motivated to employ dihydrotestosterone propionate with a second active agent such as spiroperidol, in the dosage range and regimen herein, in the method of treating female sexual dysfunction because all of the dihydrootestosterone esters are known to be useful in treating female sexual dysfunction. Employing dihydrotestosterone propionate would have been reasonably expected to be similarly useful for treating female sexual dysfunction. Employing a second active agent such as spiroperidol into the method of treating

female sexual dysfunction would have been reasonably expected to be effective based on the teachings of the cited prior art. Combining two or more agents which are known to be useful to treat female sexual dysfunction individually into a single composition and method useful for the very same purpose is prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan. The skilled of artisan would possess all conventional administration method of the active compounds such as parenteral administration. The selection of one or another route of administration would be seen as a simple selection from among obvious alternatives.

Response to Arguments

Applicant's arguments with respect to claims 1-12,16-18, 20-24, 26-28, 43, and 50 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617